K011283

OCT 1 5 2001

EXHIBIT # 8

510(k) Summary

Kendall Monoject® PreFill 0.9% Sodium Chloride Flush Syringe

In accordance with section 513(I) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

The Kendall Company
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: April 9, 2001

1. Contact Person

David A. Olson
Director, Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

Classification Name:	Catheter, Intravascular, Therapeutic, Short-Term
Common or Usual Name:	Monoject® PreFill 0.9% Sodium Chloride Flush Syringe

3. Identification of Legally Marketed Device

The proposed Kendall Monoject® PreFill Flush Syringe is substantially equivalent in intended use, function and composition to Baxter Healthcare Corporations' 0.9% Sodium Chloride Flush Syringe, 510(k) No. K984590 and BD/Prefill Normal Saline Flush Syringe, 510(k) No. K982558.

4. Device Description

The proposed device is a sterile, single use, standard piston syringe of various sizes and fill volumes containing 0.9% Sodium Chloride Injection, USP.

5. Device Intended Use

The proposed device is indicated for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.

6. Product Comparison

The proposed device has the same technological characteristics as the predicate devices. Each consists of Monoject® plastic syringes containing 0.9% Sodium Chloride solution.

7. Nonclinical Testing

Biocompatibility testing of the proposed device has demonstrated that it meets the requirements of guidelines presented in the 10993 ISO Standard, Part 1, with the FDA modified matrix presented in memorandum G95-1.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 2001

The Kendall Company
C/O Mr. David A. Olson
Director, Regulatory Affairs
Division of Tyco Healthcare Group LP
15 Hampshire Street
Mansfield, Massachusetts 02048

Re: K011283
Trade/Device Name: Monojet Prefill 0.9% Soduim Chloride Flush Syringe
Regulation Number: 880.5200
Regulation Name: Catheter, Intravascular, Therapeutic, Short-Term
Regulatory Class: II
Product Code: NGT
Dated: August 8, 2001
Received: August 10, 2001

Dear Mr. Olson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011283

510(k) Number (if known):_____

Device Name: Monoject Prefill 0.9% Sodium Chloride Flush Syringe

Indications For Use:

The 0.9% Sodium Chloride Flush Syringe is indicated for use in flushing compatible intravenous tubing systems and indwelling intravascular access devices.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) B. Butler
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011283

Prescription Use_____ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)